

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **52R**

Lot-specific information
Olerup SSP[®] DRB3

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Product number: 101.121-24/04 – including *Taq* pol.
 101.121-24u/04u – without *Taq* pol.

Lot number: 52R

Expiry date: 2015-April-01

Number of tests: 24 tests – Product No. 101.121-24/24u
 4 tests – Product No. 101.121-04/04u

Number of wells per test: 32

Storage - pre-aliquoted primers: dark at -20°C

- PCR Master Mix: -20°C
- Adhesive PCR seals: RT
- Product Insert: RT

This Product Description is only valid for Lot No. 52R.

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®]
 DRB3 LOT(71M)**

Two wells have been added to the DRB3 kit, wells **31 and 32**.

The Lot-specific information for DRB3 including and without *Taq* polymerase is now described in one common Product Insert.

The DRB3 primer set as well as the specificity and interpretation tables have been updated for the DRB alleles described since the previous *Olerup SSP[®] DRB3* lot (**Lot No. 71M**) was made.

The primers of the wells detailed below have been exchanged, added or modified compared to the previous lot.

Well	5'-primer	3'-primer	rationale
31	New	New	New primer pair for the DRB3*02:29N allele.
32	New	New	New primer pair for improved allelic resolution.

Change in revision R01 compared to R00:

1. The DRB3*02:15 and DRB3*02:27 and the DRB1*08:32, 12:01:02-12:01:03, 12:02:02, 12:03:02, 12:16:01, 14:121, 15:03:01:01-15:03:02, 15:23, 15:54 and 15:57 alleles are weakly amplified by primer mix 10. This has been corrected in the specificity and interpretation tables.

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PRODUCT DESCRIPTION

DRB3 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB3*01:01 to DRB3*03:03 alleles.

PLATE LAYOUT

Each test consists of 32 PCR reactions in a 32 well cut PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24
25	26	27	28	29	30	31	32

The 32 well cut PCR plate is marked with 'DRB3' in silver/gray ink.

Well No. 1 is marked with the Lot No. '52R'.

A faint row of numbers is seen between wells 1 and 2 or wells 7 and 8 of the PCR trays. These stem from the manufacture of the trays, and should be disregarded.

The PCR plates are covered with a PCR-compatible foil.

Please note: When removing each 32 well PCR plate, make sure that the remaining plates stay covered. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

The interpretation of DRB3 subtypings will be influenced by fifteen DRB1*03 alleles, two DRB1*04, four DRB1*08, the DRB1*10, seven DRB1*11, three DRB1*12, twelve DRB1*13 alleles, ten DRB1*14 and the DRB1*15:65 alleles. Thus, the interpretation of DRB3 subtypings is only marginally influenced by other DRB genes.

UNIQUELY IDENTIFIED ALLELES

All the DRB3 alleles, i.e. **DRB3*01:01 to DRB3*01:15, DRB3*02:01 to DRB3*02:29N and DRB3*03:01 to DRB3*03:03**, recognized by the HLA Nomenclature Committee in July 2012¹ will give rise to unique amplification patterns by the primers in the DRB3 subtyping kit.

The DRB3 subtyping kit cannot distinguish the silent mutations in the DRB3*01:01:02:01 to 01:01:05 alleles, the DRB3*02:02:01 to 02:02:05 alleles or the DRB3*03:01:01 to 03:01:03 alleles.

¹DRB alleles listed on the IMGT/HLA web page 2012-July-12, release 3.9.0, www.ebi.ac.uk/imgt/hla.

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RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 58 alleles generate 47 amplification patterns that can be combined in 1128 homozygous and heterozygous combinations. 288 of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR products were not considered in these calculations.

-----	+-----	-----	-----	*02:15, *02:27 = *02:27, *02:27
-----	++++--	-----	-----	*02:02:01:01, *02:29N = *02:29N, *02:29N
-----	++++--	-----	-----	*02:02:01:01, *02:28 = *02:28, *02:28
-----	++++--	-----	+-----	*02:02:01:01, *02:26 = *02:26, *02:26
-----	++++--	-----	+-----	*02:02:01:01, *02:13 = *02:13, *02:13
-----	++++--	-----	+-----	*02:02:01:01, *02:12 = *02:12, *02:12
-----	++++--	-----	+-----	*02:02:01:01, *02:11 = *02:11, *02:11
-----	++++--	-----	-----	*02:02:01:01, *02:08 = *02:02:01:01, *02:14 = *02:08, *02:08 = *02:08, *02:14
-----	++++--	+-----	-----	*02:02:01:01, *02:07 = *02:07, *02:07
-----	++++--	+-----	-----	*02:02:01:01, *02:06 = *02:02:01:01, *02:20 = *02:06, *02:06 = *02:06, *02:20
-----	++++--	-----	-----	*02:02:01:01, *02:22 = *02:22, *02:22
-----	++++--	-----	+-----	*02:01, *02:01 = *02:01, *02:24
-----	++++--	-----	-----	*02:04, *02:04 = *02:04, *02:24
-----	+-----	+-----	-----	*02:09, *02:09 = *02:09, *02:10
-----	+-----	+-----	-----	*01:09, *01:09 = *01:09, *02:10
-----	++++--	-----	+-----	*02:02:01:01, *02:25 = *02:25, *02:25
-----	++++--	-----	+-----	*02:08, *02:29N = *02:14, *02:29N
-----	++++--	-----	+-----	*02:08, *02:28 = *02:14, *02:28
-----	++++--	-----	+-----	*02:08, *02:15 = *02:14, *02:15
-----	++++--	-----	+-----	*02:08, *02:26 = *02:14, *02:26
-----	++++--	-----	+-----	*02:02:01:01, *02:18 = *02:08, *02:18 = *02:14, *02:18 = *02:18, *02:18
-----	++++--	-----	+-----	*02:08, *02:13 = *02:13, *02:14
-----	++++--	-----	+-----	*02:08, *02:12 = *02:12, *02:14
-----	++++--	-----	+-----	*02:08, *02:11 = *02:11, *02:14
-----	++++--	-----	+-----	*02:08, *02:10 = *02:10, *02:14
-----	++++--	-----	+-----	*02:07, *02:08 = *02:07, *02:14
-----	++++--	+-----	+-----	*02:06, *02:29N = *02:20, *02:29N
-----	++++--	+-----	+-----	*02:06, *02:28 = *02:20, *02:28
-----	++++--	+-----	+-----	*02:06, *02:15 = *02:15, *02:20
-----	++++--	+-----	+-----	*02:06, *02:26 = *02:20, *02:26
-----	++++--	+-----	+-----	*02:06, *02:13 = *02:13, *02:20
-----	++++--	+-----	+-----	*02:06, *02:12 = *02:12, *02:20
-----	++++--	+-----	+-----	*02:06, *02:11 = *02:11, *02:20
-----	++++--	+-----	+-----	*02:06, *02:10 = *02:10, *02:20
-----	++++--	+-----	+-----	*02:02:01:01, *02:23 = *02:06, *02:08 = *02:06, *02:14 = *02:06, *02:23 = *02:08, *02:20 = *02:08, *02:23 = *02:14, *02:23 = *02:20, *02:23 = *02:23, *02:23
-----	++++--	+-----	+-----	*02:06, *02:07 = *02:07, *02:20
-----	++++--	+-----	+-----	*02:08, *02:22 = *02:14, *02:22
-----	++++--	+-----	+-----	*02:06, *02:22 = *02:20, *02:22
-----	++++--	-----	-----	*02:02:01:01, *02:17 = *02:03, *02:17 = *02:17, *02:17
+-----	++++--	-----	-----	*02:05, *02:08 = *02:05, *02:14
+-----	++++--	+-----	-----	*02:05, *02:06 = *02:05, *02:20
+-----	++++--	-----	-----	*01:07, *01:07 = *01:07, *02:05

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+++-----	-----+	---+-----	+-----	*01:01:02:01, *01:12 = *01:12, *01:12	
+++-----	-----+	---+-----	-----	*01:01:02:01, *01:11 = *01:11, *01:11	
+++-----	-----+	---+-----	-----	*01:01:02:01, *01:13 = *01:13, *01:13	
+++-----+	-----+	---+-----	-----	*01:01:02:01, *01:06 = *01:06, *01:06	
+++-----+	-----+	---+-----	-----	*01:01:02:01, *01:05 = *01:01:02:01, *01:15 = *01:05, *01:05 = *01:05, *01:15	
+++-----	-----+	---+-----	-----	*01:01:02:01, *01:04 = *01:04, *01:04	
+++-----	-----+	---+-----	-----	*01:01:02:01, *01:03 = *01:01:02:01, *01:10 = *01:03, *01:10 = *01:10, *01:10	
++++-----	-----+	---+-----	-----	*01:01:02:01, *01:02 = *01:02, *01:02	
-----	+++-----	---+-----	---+-----	*02:08, *02:27 = *02:14, *02:27	
-----	+++-----	---+-----	-----+	*02:08, *02:25 = *02:14, *02:25 = *02:18, *02:25	
-----	+++-----	---+-----	-----+	*02:02:01:01, *02:21 = *02:07, *02:21 = *02:07, *02:25 = *02:21, *02:21 = *02:21, *02:25	
-----	+++-----	---+-----	-----	*02:02:01:01, *02:09 = *02:07, *02:09	
-----	+++-----	---+-----	---+-----	*02:06, *02:27 = *02:20, *02:27	
-----	+++-----	---+-----	-----+	*02:06, *02:25 = *02:20, *02:25	
-----	+++-----	---+-----	-----	*02:06, *02:18 = *02:18, *02:20 = *02:18, *02:23	
-----	+++-----+	---+-----	-----+	*02:02:01:01, *02:19 = *02:19, *02:19 = *02:19, *02:22 = *02:19, *02:25 = *02:22, *02:25	
-----	+++-----+	---+-----	-----	*01:09, *02:02:01:01 = *01:09, *02:07 = *01:09, *02:22	
-----	+++-----	---+-----	-----	*02:02:01:01, *02:16 = *02:03, *02:16 = *02:06, *02:16 = *02:10, *02:16 = *02:16, *02:16 = *02:16, *02:20	
-----	+++-----	---+-----	-----	*02:08, *02:17 = *02:14, *02:17	
-----	+++-----	---+-----	-----	*02:06, *02:17 = *02:17, *02:20	
-----	+++-----+	---+-----	-----	*02:02:01:01, *02:04 = *02:04, *02:22 = *02:22, *02:24	
+++-----+	---+-----	---+-----	-----	*01:07, *01:15 = *01:15, *02:05	
+++-----+	---+-----	---+-----	-----	*01:01:02:01, *01:08 = *01:06, *01:08 = *01:08, *01:08	
+++-----+	---+-----	---+-----	---+-----	*01:05, *01:14 = *01:14, *01:15	
+++-----+	---+-----	---+-----	+-----	*01:05, *01:12 = *01:12, *01:15	
+++-----+	---+-----	---+-----	-----	*01:05, *01:11 = *01:11, *01:15	
+++-----+	---+-----	---+-----	-----	*01:05, *01:13 = *01:13, *01:15	
+++-----+	---+-----	---+-----	-----	*01:05, *01:06 = *01:06, *01:15	
+++-----+	---+-----	---+-----	-----	*01:04, *01:05 = *01:04, *01:15	
+++-----	---+-----	---+-----	+-----	*01:03, *01:12 = *01:10, *01:12	
+++-----	---+-----	---+-----	-----	*01:03, *01:11 = *01:10, *01:11	
+++-----	---+-----	---+-----	-----	*01:03, *01:13 = *01:10, *01:13	
+++-----+	---+-----	---+-----	-----	*01:03, *01:06 = *01:06, *01:10	
+++-----+	---+-----	---+-----	-----	*01:03, *01:05 = *01:03, *01:15 = *01:05, *01:10 = *01:10, *01:15	
+++-----	---+-----	---+-----	-----	*01:03, *01:04 = *01:04, *01:10	
++++-----	---+-----	---+-----	-----	*01:02, *01:05 = *01:02, *01:15	
++++-----	---+-----	---+-----	-----	*01:02, *01:03 = *01:02, *01:10	
-----	+++-----	---+-----	-----+	*02:09, *02:21 = *02:09, *02:25 = *02:10, *02:21	
-----	+++-----	---+-----	-----+	*02:08, *02:21 = *02:14, *02:21 = *02:18, *02:21	
-----	+++-----	+++-----	-----	*02:08, *02:09 = *02:09, *02:14 = *02:09, *02:18	
-----	+++-----	+++-----	-----+	*02:06, *02:21 = *02:20, *02:21	
-----	+++-----	+++-----	-----	*02:06, *02:09 = *02:09, *02:20	
-----	+++-----+	---+-----	-----+	*02:08, *02:19 = *02:14, *02:19 = *02:18, *02:19	
-----	+++-----+	---+-----	-----+	*02:07, *02:19 = *02:19, *02:21 = *02:21, *02:22	
-----	+++-----+	+++-----	-----	*01:09, *02:08 = *01:09, *02:14	
-----	+++-----+	+++-----	-----+	*02:06, *02:19 = *02:19, *02:20	
-----	+++-----+	+++-----	-----	*01:09, *02:06 = *01:09, *02:20	

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-----	++++++	+++-----	-----	*02:08, *02:16 = *02:14, *02:16 = *02:16, *02:23
+-+-----	++++++	---+-----	-----	*01:07, *02:10 = *01:15, *02:02:01:01
+-+-----	++++++	---+-----	-----	*01:07, *02:08 = *01:07, *02:14
+-+-----	++++++	+-----	-----	*01:07, *02:06 = *01:07, *02:20
++++-----	-----	---+-----	-----	*01:05, *03:03 = *01:15, *03:03
++++-----	+-----	---+-----	-----	*01:01:02:01, *01:07 = *01:05, *01:07 = *01:05, *02:05
++++-----	-----	+++-----	-----	*01:05, *01:08 = *01:08, *01:15
++++-----	-----	+++-----	-----	*01:03, *01:08 = *01:08, *01:10
-----	++++++	---+-----	-----	*01:09, *02:19 = *01:09, *02:21 = *01:09, *02:25 = *02:09, *02:19
-----	++++++	---+-----	-----	*02:08, *03:02 = *02:18, *03:02
-----	++++++	+++-----	-----	*02:06, *03:02 = *02:16, *03:02
-----	++++++	---+-----	-----	*02:04, *02:19 = *02:04, *02:25 = *02:19, *02:24
-----	++++++	---+-----	-----	*01:09, *02:04 = *01:09, *02:24
++++-----	++++++	---+-----	+-----	*01:01:02:01, *02:26 = *01:12, *02:02:01:01 = *01:12, *02:26
++++-----	++++++	---+-----	-----	*01:01:02:01, *02:12 = *01:11, *02:02:01:01 = *01:11, *02:12
++++-----	++++++	---+-----	-----	*01:01:02:01, *02:11 = *01:13, *02:02:01:01 = *01:13, *02:11
++++-----	++++++	+++-----	-----	*01:06, *02:20 = *01:08, *02:20
++++-----	---+-----	---+-----	-----	*01:05, *03:01:01 = *01:15, *03:01:01
+++++-----	+-----	---+-----	-----	*01:03, *01:07 = *01:07, *01:10
+-+-----	++++++	+++-----	-----	*01:07, *02:16 = *01:15, *02:16
++-----	++++++	---+-----	-----	*02:08, *03:03 = *02:18, *03:03
++-----	++++++	+++-----	-----	*02:06, *03:03 = *02:16, *03:03
++++-----	++++++	---+-----	+-----	*01:11, *02:26 = *01:12, *02:12
++++-----	++++++	---+-----	+-----	*01:12, *02:11 = *01:13, *02:26
++++-----	++++++	---+-----	-----	*01:11, *02:11 = *01:13, *02:12
++++-----	++++++	+++-----	-----	*01:06, *02:06 = *01:08, *02:02:01:01 = *01:08, *02:06
++-----	++++++	---+-----	-----	*02:08, *03:01:01 = *02:18, *03:01:01
++-----	++++++	+++-----	-----	*02:06, *03:01:01 = *02:16, *03:01:01
++++-----	++++++	+++-----	-----	*01:06, *02:23 = *01:08, *02:08 = *01:08, *02:23
++++-----	++++++	+++-----	-----	*01:06, *02:16 = *01:08, *02:16

*01:01:02:01 = *01:01:02:01-01:01:05
*02:02:01 = *02:02:01-02:02:05
*03:01:01 = *03:01:01-03:01:03

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SPECIFICITY TABLE

DRB3 SSP subtyping

Specificities and sizes of the PCR products of the 32 primer mixes used for DRB3 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DRB3 alleles ³	Amplified DRB1 ⁴ alleles
1⁵	100 bp	515 bp	*01:01:02:01-01:08, 01:10-01:13, 01:15, 02:05, 03:01:01-03:01:03, 03:03	*03:42, 11:30 ^w , 13:67, 14:46
2⁵	125 bp	430 bp	*01:01:02:01-01:06, 01:08, 01:10-01:14, 03:01:01-03:01:03, 03:03	*03:38, 03:79, 04:82 ^w , 04:99 ^w , 08:07 ^w , 08:19 ^w , 08:25 ^w , 08:34 ^w , 12:27 ^w , 13:31 ^w , 13:46 ^w , 13:54 ^w , 13:77 ^w , 13:100 ^w , 14:48
3⁵	95 bp	430 bp	*01:01:02:01-01:02, 01:04-01:08, 01:10-01:13, 01:15	*03:42
4	265 bp	430 bp	*01:02	
5^{5,8}	95 bp, 125 bp	430 bp	*01:03, 01:10	*14:46
6	190 bp	430 bp	*01:04	
7^{5,9}	90 bp, 180 bp	515 bp	*01:05, 01:07, 01:15	*03:42, 14:46
8⁵	120 bp	430 bp	*01:06, 01:08	*03:42, 14:46
9⁶	165 bp	430 bp	*01:07, 02:01-02:08, 02:11-02:29N	
10⁶	185 bp	515 bp	*01:09, 02:01-02:04, 02:06-02:14, 02:15 ^w , 02:16-02:26, 02:27 ^w , 02:28-02:29N, 03:02	08:32 ^w , 12:01:02 ^w -12:01:03 ^w , 12:02:02 ^w , 12:03:02 ^w , 12:16:01 ^w , 12:22 ^w , 14:121 ^w , 15:03:01:01 ^w -15:03:02 ^w , 15:23 ^w , 15:54 ^w , 15:57 ^w
11	270 bp	515 bp	*02:01, 02:04, 02:24, 03:01:01-03:02	*03:42
12^{5,10}	90 bp, 145 bp	515 bp	*02:01, 02:04, 02:17, 02:24	*03:37, 03:80, 11:43, 11:50, 11:115, 12:34, 13:131, 14:59, 14:86, 14:96, 15:65

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13⁶	270 bp	515 bp	*01:01:02:01-01:13, 01:15, 02:02:01:01-02:03, 02:05-02:13, 02:15-02:23, 02:25-02:29N, 03:03	*11:30, 13:67, 14:46
14	185 bp	515 bp	*01:07, 01:09, 02:02:01:01-02:02:05, 02:05-02:13, 02:15-02:19, 02:21-02:23, 02:25-02:29N	*10:01:01 ^w -10:01:03 ^w , 10:03 ^w -10:04 ^w
15^{5,11}	120 bp, 180 bp, 210 bp	430 bp	*02:03, 02:16-02:17, 03:01:01-03:03	
16	150 bp	430 bp	*01:09, 02:04, 02:19, 02:22	*03:44
17^{5,12}	120 bp, 180 bp	430 bp	*01:08, 02:06, 02:16, 02:20, 02:23	*03:42, 13:67, 14:46
18⁵	100 bp	430 bp	*01:09, 02:07, 02:09, 02:21	
19^{7,13}	180 bp, 270 bp	515 bp	*02:08, 02:14, 02:18, 02:23	*11:30
20¹⁴	165 bp, 180 bp	430 bp	*01:01:02:01-01:06, 01:08-01:13, 01:15, 02:09-02:10, 02:16, 03:01:01-03:03	*03:42, 11:30, 13:67, 14:46
21^{5,15}	120 bp, 210 bp	430 bp	*01:13, 02:11	
22¹⁶	185 bp, 245 bp	430 bp	*01:11, 02:12	
23	195 bp	430 bp	*02:13	
24	185 bp	430 bp	*02:09, 02:18-02:19, 02:21, 02:25, 03:01:01-03:03	*11:30
25¹⁷	225 bp, 260 bp	430 bp	*01:12, 02:26	
26	235 bp	430 bp	*01:14	*03:01:02, 03:02:02, 03:05:03, 03:13:02, 03:17, 03:24, 03:27, 03:35, 03:81, 11:27:01, 11:84:01, 11:124, 12:22, 13:33:02-13:33:03, 13:61:01, 13:96:02, 14:38, 14:47, 14:50, 14:98, 14:127
27⁵	90 bp	430 bp	*02:01	

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Lot No.: 52R		Lot-specific information		www.olerup-ssp.com
28	235 bp	430 bp	*02:27	*11:30, 13:67, 14:46
29	160 bp	430 bp	*02:15, 02:27	*10:01:01 ^w -10:04 ^w , 13:106
30	210 bp	430 bp	*02:28	
31 ⁵	90 bp	430 bp	*02:29N	
32 ⁵	70 bp	430 bp	*02:19, 02:21, 02:25	*12:34

¹Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of DRB3 SSP typings.

When the primers in a primer mix can give rise to HLA-specific PCR products of more than one length this is indicated if the size difference is more than 20 base pairs. Size differences of 20 base pairs or less are not given. For high resolution SSP kits the respective lengths of the HLA-specific PCR product(s) are given for the alleles amplified by these primer mixes.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.

PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 430 base pairs, for most wells, or a band of 515 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to help in the correct orientation of the DRB3 subtyping.

In addition, wells number 7, 10 to 14 and 19 contain the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

In the presence of a specific amplification the intensity of the control band often decreases.

³For several DRB alleles 1st and/or 3th exon(s) and above, as well as intron nucleotide sequences, are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in these regions are conserved within allelic groups and that unknown sequences of codons 87 to 92 are identical with the DRB1*0101 consensus sequence.

⁴Due to the sharing of sequence motifs between DRB3 and DRB1 alleles, primer mixes 1 to 3, 5, 7, 8, 10 to 14, 16, 17, 19, 20, 24, 26, 28, 29 and 32 will amplify DRB1 alleles.

⁵HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

⁶Primer mixes 9, 10 and 13 may have tendencies of unspecific amplifications.

⁷Primer mix 19 has a tendency to giving rise to primer oligomer formation.

⁸Primer mix 5: Specific PCR fragment of 95 bp in the DRB3*01:03 and the DRB1*14:46 alleles. Specific PCR fragment of 125 bp in the DRB3*01:10 allele.

⁹Primer mix 7: Specific PCR fragment of 90 bp in the DRB3*01:05 allele. Specific PCR fragment of 180 bp in the DRB3*01:07 and 01:15 and in the DRB1*03:42 and DRB1*14:46 alleles.

¹⁰Primer mix 12: Specific PCR fragment of 90 bp in the DRB3*02:17 allele. Specific PCR fragment of 145 bp in the DRB3*02:01, 02:04 and 02:24 and in the DRB1*03:37, DRB1*03:80, DRB1*11:43, DRB1*11:50, DRB1*11:115, DRB1*12:34, DRB1*13:131, DRB1*14:59, DRB1*14:86, DRB1*14:96 and DRB1*15:65 alleles.

¹¹Primer mix 15: Specific PCR fragment of 120 bp DRB3*02:03 and 03:01:01-03:03 alleles. Specific PCR fragment of 180 bp in the DRB3*02:16 allele. Specific PCR fragment of 210 bp in the DRB3*02:17 allele.

101.121-24/04 – including *Taq* pol., IFU-01
101.121-24u/04u – without *Taq* pol., IFU-02

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¹²Primer mix 17: Specific PCR fragment of 120 bp in the DRB3*01:08, 02:06 and 02:20 and the DRB1*03:42, DRB1*13:67 and DRB1*14:46 alleles. Specific PCR fragment of 180 bp in the DRB3*02:16 and 02:23 alleles.

¹³Primer mix 19: Specific PCR fragment of 180 bp in the DRB3*02:08, 02:18 and 02:23 and the DRB1*11:30 alleles. Specific PCR fragment of 270 bp in the DRB3*02:14 allele.

¹⁴Primer mix 20: Specific PCR fragment of 165 bp in the DRB3*01:01:02:01-01:06, 01:08-01:13, 01:15, 02:09-02:10 and 03:01:01-03:03 and the DRB1*03:42, DRB1*11:30, DRB1*13:67 and DRB1*14:46 alleles. Specific PCR fragment of 180 bp in the DRB3*02:16 allele.

¹⁵Primer mix 21: Specific PCR fragment of 120 bp in the DRB3*01:13 allele. Specific PCR fragment of 210 bp in the DRB3*02:11 allele.

¹⁶Primer mix 22: Specific PCR fragment of 185 bp in the DRB3*01:11 allele. Specific PCR fragment of 245 bp in the DRB3*02:12 allele.

¹⁷Primer mix 25: Specific PCR fragment of 225 bp in the DRB3*02:26 allele. Specific PCR fragment of 260 bp in the DRB3*01:12 allele.

'w', might be weakly amplified.

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

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Lot-specific information

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INTERPRETATION TABLE																
DRB3 SSP subtyping																
Amplification patterns of the DRB3*01:01 to *03:03 alleles																
	Well ⁵															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Length of spec. PCR product(s)	100	125	95	265	95	190	90	120	165	185	270	90	270	185	120	150
Length of int. pos. control ¹	515	430	430	430	430	430	515	430	430	515	515	515	515	515	430	430
5'-primer(s) ²	10(116)	29(175)	11(119)	10(118)	11(119)	8(110)	11(119)	11(119)	10(116)	29(175)	10(116)	51(239)	10(116)	38(200)	11(119)	38(200)
	5'-gCT ^{3'}	5'-gAT ^{3'}	5'-gCg ^{3'}	5'-TgT ^{3'}	5'-gCg ^{3'}	5'-CTC ^{3'}	5'-gCg ^{3'}	5'-gCg ^{3'}	5'-gCT ^{3'}	5'-gAC ^{3'}	5'-gCT ^{3'}	5'-gAg ^{3'}	5'-gCT ^{3'}	5'-CgC ^{3'}	5'-gCT ^{3'}	5'-CgC ^{3'}
			11(119)						10(116)				10(116)	38(200)		
			5'-gTg ^{3'}						5'-gCT ^{3'}				5'-gCT ^{3'}	5'-CgC ^{3'}		
3'-primer(s) ³	29(175)	57(257)	28(171)	86(344)	28(171)	57(257)	27(169)	37(199)	51(239)	77(317)	86(344)	66(286)	86(344)	86(344)	37(197)	74(308)
	5'-gTA ^{3'}	5'-CAA ^{3'}	5'-ATg ^{3'}		5'-gCT ^{3'}		5'-CAT ^{3'}		5'-CCC ^{3'}	5'-AgT ^{3'}	5'-CCA ^{3'}	5'-gAA ^{3'}	5'-CAC ^{3'}	5'-CAC ^{3'}	5'-Cgg ^{3'}	5'-CCC ^{3'}
	29(175)	57(257)	28(171)		38(202)		57(257)			77(318)		86(344)			37(197)	
															5'-gAA ^{3'}	
															66(286)	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

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Lot No.: **52R**

Lot-specific information

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INTERPRETATION TABLE															
DRB3 SSP subtyping															
Amplification patterns of the DRB3*01:01 to *03:03 alleles															
Well ⁵															
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
120	100	180	165	120	185	195	185	225	235	90	235	160	210	90	70
180		270	180	210	245			260							
430	430	515	430	430	430	430	430	430	430	430	430	430	430	430	430
															Length of spec. PCR product(s)
															Length of int. pos. control ¹
															5'-primer(s) ²
5'-gCT ^{3'}	5'-CgC ^{3'}	5'-gCT ^{3'}	5'-gCT ^{3'}	5'-gCT ^{3'}	5'-TgC ^{3'}	5'-ggC ^{3'}	5'-gCT ^{3'}	5'-gCT ^{3'}	5'-TAC ^{3'}	5'-CAT ^{3'}	5'-gCT ^{3'}	5'-CgC ^{3'}	5'-CTg ^{3'}	5'-CAG ^{3'}	5'-gAg ^{3'}
					5'-CAT ^{3'}										
36(196)	57(257)	55(251)	51(239)	36(196)	77(318)	77(318)	58(260)	71(299)	77(317)	179(624)	74(308)	77(317)	179(624)	165(583)	60(266)
5'-gTT ^{3'}	5'-CgA ^{3'}	5'-gCA ^{3'}	5'-CCg ^{3'}	5'-gAg ^{3'}	5'-TAA ^{3'}	5'-TAA ^{3'}	5'-CCT ^{3'}	5'-gCC ^{3'}	5'-AAT ^{3'}	5'-ACg ^{3'}	5'-CCg ^{3'}	5'-Agg ^{3'}	5'-ACg ^{3'}	5'-CCg ^{3'}	5'-Agg ^{3'}
36(196)		56(256)	57(257)	66(286)			60(266)	83(337)							
5'-gTT ^{3'}		5'-gCT ^{3'}	5'-CAG ^{3'}	5'-gAT ^{3'}			5'-Agg ^{3'}	5'-CCg ^{3'}							
55(251)		58(260)													
5'-gCA ^{3'}		5'-CCT ^{3'}													
57(257)		86(344)													
5'-CAG ^{3'}		5'-CAG ^{3'}													
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
															Well No.

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

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Lot No.: 52R

Lot-specific information

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Length of spec.	100	125	95	265	95	190	90	120	165	185	270	90	270	185	120	150
PCR product					125		180					145			180	
															210	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
DRB3 allele ⁴																
*01:01:02:01-01:01:05	1	2	3										13			
*01:02	1	2	3	4									13			
*01:03	1	2			5								13			
*01:04	1	2	3			6							13			
*01:05	1	2	3				7						13			
*01:06	1	2	3					8					13			
*01:07	1		3				7		9				13	14		
*01:08	1	2	3					8					13			
*01:09										10			13	14		16
*01:10	1	2	3		5								13			
*01:11	1	2	3										13			
*01:12	1	2	3										13			
*01:13	1	2	3										13			
*01:14		2														
*01:15	1		3				7						13			
*02:01									9	10	11	12				
*02:02:01:01-02:02:05									9	10			13	14		
*02:03									9	10			13		15	
*02:04									9	10	11	12				16
*02:05	1								9				13	14		
*02:06									9	10			13	14		
*02:07									9	10			13	14		
*02:08									9	10			13	14		
*02:09										10			13	14		
*02:10										10			13	14		
*02:11									9	10			13	14		
*02:12									9	10			13	14		
*02:13									9	10			13	14		
*02:14									9	10						
*02:15									9	w			13	14		
*02:16									9	10			13	14	15	
*02:17									9	10		12	13	14	15	
*02:18									9	10			13	14		
*02:19									9	10			13	14		16
*02:20									9	10			13			
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

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Lot No.: **52R**

Lot-specific information

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120	100	180	165	120	185	195	185	225	235	90	235	160	210	90	70	Length of spec. PCR product
180		270	180	210	245			260								
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																DRB3 allele ⁴
			20													*01:01:02:01- 01:01:05
			20													*01:02
			20													*01:03
			20													*01:04
			20													*01:05
			20													*01:06
			20													*01:07
17			20													*01:08
	18		20													*01:09
			20													*01:10
			20		22											*01:11
			20					25								*01:12
			20	21												*01:13
			20						26							*01:14
			20													*01:15
									27							*02:01
																*02:02:01:01- 02:02:05
																*02:03
																*02:04
																*02:05
17																*02:06
	18															*02:07
		19														*02:08
	18		20				24									*02:09
			20													*02:10
				21												*02:11
					22											*02:12
						23										*02:13
		19														*02:14
												29				*02:15
17			20													*02:16
																*02:17
		19					24									*02:18
							24								32	*02:19
17																*02:20
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

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Lot No.: **52R**

Lot-specific information

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Length of spec.	100	125	95	265	95	190	90	120	165	185	270	90	270	185	120	150
PCR product					125		180					145			180	
															210	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*02:21									9	10			13	14		
*02:22									9	10			13	14		16
*02:23									9	10			13	14		
*02:24									9	10	11	12				
*02:25									9	10			13	14		
*02:26									9	10			13	14		
*02:27									9	w			13	14		
*02:28									9	10			13	14		
*02:29N									9	10			13	14		
*03:01:01- 03:01:03	1	2									11				15	
*03:02										10	11				15	
*03:03	1	2											13		15	
<i>DRB1</i> *03:01:02, 03:02:02, 03:05:03, 03:13:02, 03:17, 03:24, 03:27, 03:35, 03:81, 11:27:01, 11:84:01, 11:124, 13:33:02- 13:33:03, 13:61:01, 13:96:02, 14:38, 14:47, 14:50, 14:98, 14:127																
<i>DRB1</i> *03:37, 03:80, 11:43, 11:50, 11:115, 13:131, 14:59, 14:86, 14:96, 15:65												12				
<i>DRB1</i> *03:38, 03:79, 14:48		2														
<i>DRB1</i> *03:42	1		3				7	8			11					
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

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Lot No.: **52R**

Lot-specific information

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120	100	180	165	120	185	195	185	225	235	90	235	160	210	90	70	Length of spec. PCR product
180		270	180	210	245			260								
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
	18						24								32	*02:21
																*02:22
17		19														*02:23
																*02:24
							24								32	*02:25
								25								*02:26
										28	29					*02:27
													30			*02:28
														31		*02:29N
			20				24									*03:01:01- 03:01:03
			20				24									*03:02
			20				24									*03:03
									26							<i>DRB1</i> *03:01:02, 03:02:02, 03:05:03, 03:13:02, 03:17, 03:24, 03:27, 03:35, 03:81, 11:27:01, 11:84:01, 11:124, 13:33:02- 13:33:03, 13:61:01, 13:96:02, 14:38, 14:47, 14:50, 14:98, 14:127
																<i>DRB1</i> *03:37, 03:80, 11:43, 11:50, 11:115, 13:131, 14:59, 14:86, 14:96, 15:65
																<i>DRB1</i> *03:38, 03:79, 14:48
17			20													<i>DRB1</i> *03:42
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

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Lot No.: **52R**

Lot-specific information

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Length of spec.	100	125	95	265	95	190	90	120	165	185	270	90	270	185	120	150
PCR product					125		180					145			180	
															210	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
DRB1*03:44																16
DRB1*04:82, 04:99, 08:07, 08:19, 08:25, 08:34, 12:27, 13:31, 13:46, 13:54, 13:77, 13:100		w														
DRB1*08:32, DRB1*12:01:02- 12:01:03, 12:02:02, 12:03:02, 12:16:01, DRB1*14:121, DRB1*15:03:01:0 1-15:03:02, 15:23, 15:54, 15:57										w						
DRB1*10:01:01- 10:01:03, 10:03- 10:04														w		
DRB1*10:02																
DRB1*11:30	w												13			
DRB1*12:22										w						
DRB1*12:34												12				
DRB1*13:67	1												13			
DRB1*13:106																
DRB1*14:46	1				5		7	8					13			
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 430 base pairs, for most wells, or a band of 515 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to help in the correct orientation of the DRB3subtyping.

In addition, wells number wells number 7, 10 to 14 and 19 contain the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

In the presence of a specific amplification the intensity of the control band often decreases.

²The codon, and in parenthesis the nucleotide, in the 2nd and 3rd exon, matching the specificity-determining 3'-end of the primer is given. Codon and nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

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Lot-specific information

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120	100	180	165	120	185	195	185	225	235	90	235	160	210	90	70	Length of spec. PCR product
180		270	180	210	245			260								
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																<i>DRB1*03:44</i>
																<i>DRB1*04:82, 04:99, 08:07, 08:19, 08:25, 08:34, 12:27, 13:31, 13:46, 13:54, 13:77, 13:100</i>
																<i>DRB1*08:32, DRB1*12:01:02- 12:01:03, 12:02:02, 12:03:02, 12:16:01, DRB1*14:121, DRB1*15:03:01:0 1-15:03:02, 15:23, 15:54, 15:57</i>
												w				<i>DRB1*10:01:01- 10:01:03, 10:03- 10:04</i>
												w				<i>DRB1*10:02</i>
		19	20				24				28					<i>DRB1*11:30</i>
									26							<i>DRB1*12:22</i>
															32	<i>DRB1*12:34</i>
17			20								28					<i>DRB1*13:67</i>
												29				<i>DRB1*13:106</i>
17			20								28					<i>DRB1*14:46</i>
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

³The codon, and in parenthesis the nucleotide, in the 2nd and 3rd exon, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Codon and nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

⁴DRB3*010101 allele has been shown to be identical to DRB3*01:01:02:01

⁵Primer mix 5: Specific PCR fragment of 95 bp in the DRB3*01:03 and the DRB1*14:46 alleles. Specific PCR fragment of 125 bp in the DRB3*01:10 allele.

Primer mix 7: Specific PCR fragment of 90 bp in the DRB3*01:05 allele. Specific PCR fragment of 180 bp in the DRB3*01:07 and 01:15 and in the DRB1*03:42 and DRB1*14:46 alleles.

101.121-24/04 – including *Taq* pol., IFU-01
101.121-24u/04u – without *Taq* pol., IFU-02

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Lot No.: **52R**

Lot-specific information

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Primer mix 12: Specific PCR fragment of 90 bp in the DRB3*02:17 allele. Specific PCR fragment of 145 bp in the DRB3*02:01, 02:04 and 02:24 and in the DRB1*03:37, DRB1*03:80, DRB1*11:43, DRB1*11:50, DRB1*11:115, DRB1*12:34, DRB1*13:131, DRB1*14:59, DRB1*14:86, DRB1*14:96 and DRB1*15:65 alleles.

Primer mix 15: Specific PCR fragment of 120 bp DRB3*02:03 and 03:01:01-03:03 alleles. Specific PCR fragment of 180 bp in the DRB3*02:16 allele. Specific PCR fragment of 210 bp in the DRB3*02:17 allele.

Primer mix 17: Specific PCR fragment of 120 bp in the DRB3*01:08, 02:06 and 02:20 and the DRB1*03:42, DRB1*13:67 and DRB1*14:46 alleles. Specific PCR fragment of 180 bp in the DRB3*02:16 and 02:23 alleles.

Primer mix 19: Specific PCR fragment of 180 bp in the DRB3*02:08, 02:18 and 02:23 and the DRB1*11:30 alleles. Specific PCR fragment of 270 bp in the DRB3*02:14 allele.

Primer mix 20: Specific PCR fragment of 165 bp in the DRB3*01:01:02:01-01:06, 01:08-01:13, 01:15, 02:09-02:10 and 03:01:01-03:03 and the DRB1*03:42, DRB1*11:30, DRB1*13:67 and DRB1*14:46 alleles. Specific PCR fragment of 180 bp in the DRB3*02:16 allele.

Primer mix 21: Specific PCR fragment of 120 bp in the DRB3*01:13 allele. Specific PCR fragment of 210 bp in the DRB3*02:11 allele.

Primer mix 22: Specific PCR fragment of 185 bp in the DRB3*01:11 allele. Specific PCR fragment of 245 bp in the DRB3*02:12 allele.

Primer mix 25: Specific PCR fragment of 225 bp in the DRB3*02:26 allele. Specific PCR fragment of 260 bp in the DRB3*01:12 allele.

'w', might be weakly amplified.

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

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Lot No.: **52R**

Lot-specific information

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CELL LINE VALIDATION SHEET																				
DRB3 SSP subtyping kit																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.	201190801	201080502	201080503	201080504	201080505	201080506	201190807	201080508	201080509	201080510	201080511	201080512	201080513	201080514	201080515	201190816
IHCW cell line		DRB3																		
1	9001	SA		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
2	9280	LK707		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
3	9011	E4181324		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
4	9275	GU373	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-	
5	9009	KAS011		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
6	9353	SM		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
7	9020	QBL	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-	
8	9025	DEU		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
9	9026	YAR		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
10	9107	LKT3		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
11	9051	PITOUT		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
12	9052	DBB		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
13	9004	JESTHOM		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
14	9071	OLGA		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
15	9075	DKB		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
16	9037	SWEIG007	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-	
17	9282	CTM3953540	*01:01	+	+	+	-	-	-	-	-	-	-	-	-	+	+	-	-	
18	9257	32367	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-	
19	9038	BM16	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-	
20	9059	SLE005	*03:01	+	+	-	-	-	-	-	-	-	-	+	-	-	-	+	-	
21	9064	AMALA	*01:01	+	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-	
22	9056	KOSE	*02:02	+	+	-	-	-	-	-	-	+	+	+	-	+	+	+	-	
23	9124	IHL	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-	
24	9035	JBUSH	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-	
25	9049	IBW9		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
26	9285	WT49	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-	
27	9191	CH1007 ¹		-	-	-	-	-	-	-	-	-	-	-	-	-	w	-	-	
28	9320	BEL5GB		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
29	9050	MOU		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
30	9021	RSH	*01:01	+	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-	
31	9019	DUCAF	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-	
32	9297	HAG	*01:01	+	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-	
33	9098	MT14B		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
34	9104	DHIF	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-	
35	9302	SSTO		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
36	9024	KT17		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
37	9065	HHKB	*01:01	+	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-	
38	9099	LZL	*01:01	+	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-	
39	9315	CML	*01:01	+	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-	
40	9134	WHONP199		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
41	9055	H0301	*03:01	+	+	-	-	-	-	-	-	-	-	+	-	-	-	+	-	
42	9066	TAB089		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
43	9076	T7526		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
44	9057	TEM	*02:01	-	-	-	-	-	-	-	-	+	+	+	+	-	-	-	-	
45	9239	SHJO		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
46	9013	SCHU		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
47	9045	TUBO	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-	
48	9303	TER-ND		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	

¹The DRB1*10:01 allele is weakly amplified by primer mix 14 in the CH1007 cell line.

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

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Lot No.: **52R**

Lot-specific information

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CELL LINE VALIDATION SHEET																				
DRB3 SSP subtyping kit																				
				Well																
				17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	
				Prod. No.	201080517	201080518	201080519	201080520	201080521	201209822	201209823	201080524	201190825	201080526	201080527	201190828	201190829	201190830	201209831	201209832
IHCW cell line		DRB3																		
1	9001	SA		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
2	9280	LK707		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
3	9011	E4181324		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
4	9275	GU373	*02:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
5	9009	KAS011		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
6	9353	SM		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
7	9020	QBL	*02:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
8	9025	DEU		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
9	9026	YAR		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
10	9107	LKT3		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
11	9051	PITOUT		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
12	9052	DBB		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
13	9004	JESTHOM		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
14	9071	OLGA		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
15	9075	DKB		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
16	9037	SWEIG007	*02:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
17	9282	CTM3953540	*01:01	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	
18	9257	32367	*02:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
19	9038	BM16	*02:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
20	9059	SLE005	*03:01	-	-	-	+	-	-	-	+	-	-	-	-	-	-	-	-	
21	9064	AMALA	*01:01	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	
22	9056	KOSE	*02:02	*03:01	-	-	-	+	-	-	-	+	-	-	-	-	-	-	-	
23	9124	IHL	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
24	9035	JBUSH	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
25	9049	IBW9			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
26	9285	WT49	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
27	9191	CH1007			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
28	9320	BEL5GB			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
29	9050	MOU			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
30	9021	RSH	*01:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	
31	9019	DUCAF	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
32	9297	HAG	*01:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	
33	9098	MT14B			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
34	9104	DHIF	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
35	9302	SSTO			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
36	9024	KT17			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
37	9065	HHKB	*01:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	
38	9099	LZL	*01:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	
39	9315	CML	*01:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	
40	9134	WHONP199			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
41	9055	H0301	*03:01		-	-	-	+	-	-	-	+	-	-	-	-	-	-	-	
42	9066	TAB089			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
43	9076	T7526			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
44	9057	TEM	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
45	9239	SHJO			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
46	9013	SCHU			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
47	9045	TUBO	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
48	9303	TER-ND			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	



101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

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Lot No.: **52R**

Lot-specific information

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CERTIFICATE OF ANALYSIS

Olerup SSP® DRB3 SSP

Product number: 101.121-24/04 – including *Taq* pol.
 101.121-24u/04u – without *Taq* pol.
 Lot number: 52R
 Expiry date: 2015-April-01
 Number of tests: 24 tests – Product No. 101.121-24/24u
 4 tests – Product No. 101.121-04/04u
 Number of wells per test: 32

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2011-908-01	13	2010-805-13	25	2011-908-25
2	2010-805-02	14	2010-805-14	26	2010-805-26
3	2010-805-03	15	2010-805-15	27	2010-805-27
4	2010-805-04	16	2011-908-16	28	2011-908-28
5	2010-805-05	17	2010-805-17	29	2011-908-29
6	2010-805-06	18	2010-805-18	30	2011-908-30
7	2011-908-07	19	2010-805-19	31	2012-098-31
8	2010-805-08	20	2010-805-20	32	2012-098-32
9	2010-805-09	21	2010-805-21		
10	2010-805-10	22	2012-098-22		
11	2010-805-11	23	2012-098-23		
12	2010-805-12	24	2010-805-24		

The specificity of each primer solution of the kit has been tested against 48 well characterized cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 4 to 8, 16 to 19, 21 to 23 and 25 to 32 were available. The specificities of the primers in primer solutions 5, 7, 8, 16 to 19, 21, 25, 26, 28, 29 and 32 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 4, 6, 22, 23, 27 and 30 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solution 31 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. One or two of the 3'-primers in primer solutions 1 to 3, 5, 7, 12, 15, 17, 19, 21 and 25 were not possible to test. In primer solutions 2 and 3 one of the 5'-primers was not possible to test. Additional 3'-primers in primer solutions 15, 20 and 24 were tested by separately adding one 5'-primer.

Results: No false positive or false negative amplifications were obtained.

Date of approval: 2012- November-26

Approved by:

Production Quality Control

101.121-24/04 – including *Taq* pol., IFU-01
101.121-24u/04u – without *Taq* pol., IFU-02

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Lot No.: **52R**

Lot-specific information

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Declaration of Conformity

Product name: *Olerup* SSP® DRB3
Product number: 101.121-24/24u, -04/04u
Lot number: 52R

Intended use: DRB3 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
Franzengatan 5
SE-112 51 Stockholm, Sweden
Phone: +46-8-717 88 27
Fax: +46-8-717 88 18

We, *Olerup* SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2008 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, conformity assessed using Annex IV, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at *Olerup* SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Stockholm, Sweden
2012-November-26

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.121-24/04 – including *Taq* pol., IFU-01
101.121-24u/04u – without *Taq* pol., IFU-02

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Lot No.: **52R**

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101.121-24u/04u – without *Taq* pol., IFU-02

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Lot No.: **52R**

Lot-specific information

www.olerup-ssp.com

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